No. 14-50928

UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

WHOLE WOMAN'S HEALTH; AUSTIN WOMEN'S HEALTH CENTER; KILLEEN WOMEN'S HEALTH CENTER; NOVA HEALTH SYSTEMS, DOING BUSINESS AS REPRODUCTIVE SERVICES; SHERWOOD C. LYNN, JR.,M.D., ON BEHALF OF THEMSELVES AND THEIR PATIENTS; PAMELA J. RICHTER, D.O., ON BEHALF OF THEMSELVES AND THEIR PATIENTS; LENDOL L. DAVIS, M.D., ON BEHALF OF THEMSELVES AND THEIR PATIENTS,

Plaintiffs-Appellees,

v.

DAVID LAKEY, M.D., COMMISSIONER OF THE TEXAS DEPARTMENT OF STATE HEALTH SERVICES, IN HIS OFFICIAL CAPACITY; MARI ROBISON, EXECUTIVE DIRECTOR OF THE TEXAS MEDICAL BOARD, IN HER OFFICIAL CAPACITY,

Defendants-Appellants.

On Appeal from the United States District Court
for the Western District of Texas, Austin Division
(No. 14-CV-00284-LY, Hon. Lee Yeakel)

Amicus Curiae Brief of
Alliance Defending Freedom, Life Legal Defense Foundation, Texas Center for Defense of Life, American Association of Pro-Life Obstetricians & Gynecologists, Donna Harrison, M.D., Abby Johnson, And Then There Were None, Carol Everett, and The Heidi Group
in Support of Defendants-Appellants and
Reversal of District Court

Catherine Short
LIFE LEGAL DEFENSE FOUNDATION
P.O. Box 2105
Napa, CA 94558
Telephone: (707) 224-6675
Facsimile: (707) 224-6676
LLDFOjai@cs.com

Michael J. Norton
Counsel of Record for Amici Curiae
Natalie L. Decker
ALLIANCE DEFENDING FREEDOM
7951 E. Maplewood Ave., Suite 100
Greenwood Village, CO 80111
Telephone: (720) 689-2410
Facsimile: (303) 694-0703
mjnorton@alliancedefendingfreedom.org
ndecker@alliancedefendingfreedom.org

Stephen Casey
Gregory R. Terra
TEXAS CENTER FOR DEFENSE OF LIFE
501 S. Austin Ave., Suite 1130
Georgetown, Texas 78626
Telephone: (512) 763- 9068
Stephen@tcdl.org
greg@tcdl.org

Steven H. Aden
Catherine Glenn Foster
ALLIANCE DEFENDING FREEDOM
801 G Street NW Suite 509
Washington, DC 20001
Telephone: (202) 393-8690
saden@alliancedefendingfreedom.org
cfoster@alliancedefendingfreedom.org

No. 14-50928

UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

WHOLE WOMAN'S HEALTH; AUSTIN WOMEN'S HEALTH CENTER; KILLEEN WOMEN'S HEALTH CENTER; NOVA HEALTH SYSTEMS, DOING BUSINESS AS REPRODUCTIVE SERVICES; SHERWOOD C. LYNN, JR., M.D., ON BEHALF OF THEMSELVES AND THEIR PATIENTS; PAMELA J. RICHTER, D.O., ON BEHALF OF THEMSELVES AND THEIR PATIENTS; LENDOL L. DAVIS, M.D., ON BEHALF OF THEMSELVES AND THEIR PATIENTS,

Plaintiffs-Appellees,

v.

DAVID LAKEY, M.D., COMMISSIONER OF THE TEXAS DEPARTMENT OF STATE HEALTH SERVICES, IN HIS OFFICIAL CAPACITY; MARI ROBISON, EXECUTIVE DIRECTOR OF THE TEXAS MEDICAL BOARD, IN HER OFFICIAL CAPACITY,

Defendants-Appellants.

CERTIFICATE OF INTERESTED PERSONS

Pursuant to Fifth Circuit Rule 28.2.1, the undersigned counsel of record certifies that the following listed persons and entities as described in the fourth sentence of Rule 28.2.1 have an interest in the outcome of this case. These representations are made in order that the judges of this court may evaluate possible disqualification or recusal.

Plaintiffs-Appellees:

Whole Woman's Health

Austin Women's Health Center

Killeen Women's Health Center

Nova Health Systems doing business as Reproductive Services

Sherwood C. Lynn, Jr., M.D.

Pamela J. Richter, D.O.

Lendol L. Davis, M.D.

Plaintiffs-Appellees' attorneys:

Stephanie Toti, Center for Reproductive Rights

Esha Bhandari, Center for Reproductive Rights

Natasha Lycia Ora Bannan, Center for Reproductive Rights

David P. Brown, Center for Reproductive Rights

J. Alexander Lawrence, Morrison & Foerster LLP

Kiersten Fletcher, Morrison & Foerster LLP

Betre M. Gizaw, Morrison & Foerster LLP

Marissa P. Harris, Morrison & Foerster LLP

Colin M. O'Brien, Morrison & Foerster LLP

Jan Soifer, O'Connell & Soifer LLP

Patrick J. O'Connell & Soifer LLP

John H. Bucy, II

Defendants-Appellants:

David Lakey, M.D., Commissioner of the Texas Department of State Health Services

Mari Robinson, Executive Director of the Texas Medical Board

Defendants-Appellants' attorneys:

Texas Attorney General Gregory Abbott

Daniel T. Hodge, First Assistant Attorney General

James D. Blacklock, Deputy Attorney General

Jonathan F. Mitchell, Solicitor General

Beth Klusman, Office of the Attorney General

Philip A. Lionberger, Office of the Attorney General

Michael P. Murphy, Office of the Attorney General

Other Interested Persons or Entities:

Amici are unaware of any other interested persons or entities.

***Amici**:*

Alliance Defending Freedom

American Association of Pro-Life Obstetricians & Gynecologists

Donna Harrison, M.D.

Life Legal Defense Foundation

Texas Center for Defense of Life

Abby Johnson

And Then There Were None

Carol Everett

The Heidi Group

Attorneys for *Amici*:

Michael J. Norton, Alliance Defending Freedom

Natalie L. Decker, Alliance Defending Freedom

Steven H. Aden, Alliance Defending Freedom

Catherine Glenn Foster, Alliance Defending Freedom

Catherine Short, Life Legal Defense Foundation

Gregory R. Terra, Texas Center for Defense of Life

Stephen Casey, Texas Center for Defense of Life

Amici have no parent corporations or stock of which a publicly held corporation can hold.

s/ Michael J. Norton
Michael J. Norton
Counsel of Record for Amici Curiae
ALLIANCE DEFENDING FREEDOM
7951 E. Maplewood Ave., Suite 100
Greenwood Village, CO 80111
Telephone: (720) 689-2410
Facsimile: (303) 694-0703
mjnorton@alliancedefendingfreedom.org

Dated: November 10, 2014

Table of Contents

TABLE OF AUTHORITIES

***Cases*:**

***Statutes and Rules*:**

Other Authorities

STATEMENT OF INTEREST OF *AMICI CURIAE*[1]

Amici curiae are national organizations comprised of attorneys, doctors, and concerned individuals who have a profound interest in protecting maternal health and the sanctity of human life.

Amici include the following organizations and individuals:

Alliance Defending Freedom ("ADF") is a non-profit public interest legal organization that provides strategic planning, training, funding, and direct litigation services to protect religious freedom, the sanctity of human life, and marriage and the family. Since its founding in 1994, ADF has played a significant role, either directly or indirectly, in many cases before the U.S. Supreme Court and in hundreds more in lower courts.

ADF is deeply concerned about the sanctity of human life and the protection of the lives and health of women who choose to prematurely end the life of their unborn child. As a legal organization that often advises State and Federal legislators, ADF is also concerned about the propensity for the facts and the law in the abortion debate to be distorted, as in this case, by seeking to curtail the legitimate authority of States to protect the health and safety of their citizens by ensuring reasonable and common-sense medical care for women who may seek an

[1] In accordance with FED. R. APP. P. 29, all parties have consented to the filing of this *amicus* brief. No party's counsel has authored the brief in whole or in part. No party or party's counsel has contributed money intended to fund preparing or submitting this brief. No person other than *amici*, their members, or their counsel has contributed money that was intended to fund preparing or submitting this brief.

abortion. ADF and its allies including more than 2,200 attorneys and numerous public interest law firms and other organizations, represent hundreds of thousands of Americans who believe strongly in these issues, and who have a right to express those views through this nation's political and judicial process.

Life Legal Defense Foundation ("LLDF") is a non-profit public interest legal and educational organization that works to assist and support those who advocate in defense of life, including those whose advocacy takes place in our nation's courts and legislatures.

Texas Center for Defense of Life ("TCDL") is a non-profit legal organization formed in 2011 which defends life in state and federal courts from conception to natural death.

American Association of Pro-Life Obstetricians & Gynecologists ("AAPLOG") is a non-profit professional medical organization that consists of 2,500 obstetrician-gynecologist members and associates. AAPLOG held the title of "special interest group" within the American College/Congress of Obstetricians and Gynecologists (ACOG) from 1973 to 2013 until this designation was discontinued by ACOG. AAPLOG is concerned about the quality of care provided to pregnant women and the potential long-term adverse consequences of abortion on women's future health and explores data from around the world regarding abortion-associated complications (such as depression, substance abuse, suicide,

other pregnancy-associated mortality, subsequent preterm birth, and placenta previa) in order to provide the general public and others with a realistic appreciation and understanding of abortion-related health risks.

Donna Harrison, M.D., is the Executive Director of AAPLOG. Dr. Harrison is board certified by the American Board of Obstetrics and Gynecology. She has authored several published research articles on the topic of medication abortions, including the adverse consequences associated with RU-486. Dr. Harrison teaches physicians on complications of abortions, including medication abortions. Dr. Harrison has testified before numerous governmental bodies, including several U.S. House and Senate committees and the U.S. Food and Drug Administration.

And Then There Were None ("ATTWN") is a non-profit organization based in Texas which is devoted to providing support and training to people across the country who are disenchanted with and thus seek to leave the abortion industry. ATTWN was founded and managed by Abby Johnson.

Abby Johnson worked many years for America's largest abortion provider, Planned Parenthood, including as facility director of Planned Parenthood's Bryan, Texas abortion facility. Ms. Johnson considered herself "pro-choice" until the day she witnessed an abortion first-hand. When Ms. Johnson saw an ultrasound depiction of an unborn baby struggling to avoid the abortionist's surgical

instruments, her life was forever changed. Ultimately Ms. Johnson quit her job with Planned Parenthood, founded ATTWN in 2012, and has become one of America's leading pro-life advocates.

The Heidi Group ("THG") is a non-profit organization based in Texas that is dedicated to helping girls and women facing unplanned pregnancies make positive, life-affirming choices. THG is particularly interested in educating the people of Texas on the tactics of the abortion industry, such as tactics to avoid common sense health and safety regulations, and current issues involving abortion in Texas.

Carol Everett is the founder and president of The Heidi Group. Ms. Everett had an abortion in 1973 at age 16, shortly after the *Roe v. Wade* decision. She later ran four abortion clinics in the Dallas/Fort Worth area. After 35,000 abortions, the death of one woman, and post-abortion surgery on nineteen other women, Ms. Everett realized that abortion, her life-work to that point, was not helping women, but harming them. Ms. Everett now uses her experiences to help women facing reproductive crises see and experience positive, life-affirming options.

SUMMARY OF THE ARGUMENT

The Fifth Circuit has recognized that Texas has a legitimate interest in regulating abortion because it is a surgical or drug-induced procedure that carries significant health risks. The U.S. Supreme Court has repeatedly recognized that

abortion raises profound moral questions on which American society has not come to a consensus.[2] Thus, Texas has a legitimate interest in protecting the health and safety of women who seek abortions. In enacting House Bill 2 ("H.B.2"), [3] Texas sought to protect women's health by ensuring that physicians who terminate pregnancies are able to carefully and medically attend to the woman's health, both during and after an abortion, by having admitting privileges at a hospital within 30 miles of the location of the abortion (the "admitting privileges requirement") and by requiring that abortion facilities meet the same health and safety standards as Texas now requires of ambulatory surgical centers ("ASCs").

In Section I, *amici* discuss the legitimate interests of Texas in regulating abortions and protecting the health and safety of pregnant women. In Section II, *amici* briefly discuss H.B. 2's admitting privileges requirement. The Fifth Circuit has found this requirement to be constitutional and a legitimate regulation designed to protect women's health that does not impose an undue burden. *Amici* urge the Fifth Circuit to adopt a bright line standard concerning the availability of in-state

[2] *See, e.g.*, *Roe v. Wade*, 410 U.S. 113, 116 (1973) *(*"[T]he sensitive and emotional nature of the abortion controversy" provokes "vigorous opposing views" and inspires "deep and seemingly absolute convictions."); *Planned Parenthood of Southeastern Pennsylvania v. Casey*, 505 U.S. 833, 850 (1992) (The practice of abortion has "profound moral and spiritual implications," and "men and women of good conscience can disagree" about those implications and can find abortion "offensive to [their] most basic principles of morality."). Indeed, "there are common and respectable reasons for opposing [abortion]." *Bray v. Alexandria Women's Health Clinic*, 506 U.S. 263, 270 (1993). Further, there are "those who share an abiding moral or religious conviction (or, for that matter, simply a biological appreciation) that abortion is the taking of a human life." *Hill v. Colorado*, 530 U.S. 703, 763 (2000) (Scalia, J., dissenting).

[3] Act of July 12, 2013, 83rd Leg., 2nd C.S., ch. 1, 2013 Tex. Gen. Laws 4795.

abortions lest federal courts be drawn into being permanent monitors of the availability and status of individual abortion clinics and abortion providers in each State. In Section III, *amici* demonstrate that H.B. 2's requirement that abortion facilities meet the same standards as required of ASCs is also a legitimate regulation designed to protect the health and safety of women and does not impose an undue burden. *Amici* urge the Court to acknowledge that there is no legitimate reason to support the proposition that the quality of health and medical care provided to women in rural areas should be any lower than the quality of health and medical care available to women who reside in urban areas. The health and safety of all women, no matter where they reside, should not be compromised.

ARGUMENT

I. Texas has a legitimate state interest in regulating abortions and in protecting the health and safety of pregnant women.

In 2012, 68,298 abortions were reported in Texas. *See* 2012 Induced Terminations of Pregnancy, Texas Department of State Health Services, available at http://www.dshs.state.tx.us/chs/vstat/vs12/t38.shtm. The vast majority of the known elective abortions in Texas – 78.6 percent – were performed in abortion facilities or locations other than hospitals or ASCs. *Id.*

Because abortions involve risks to the health and safety of women, Texas has a legitimate interest in regulating abortions, abortion providers, and abortion facilities.

Long-standing precedent recognizes the strong interests and the right of States, including Texas, to regulate abortion. In *Roe v. Wade*, 410 U.S. 113, 162-64 (1973), the Supreme Court recognized two State interests: the "important interest" in protecting a pregnant woman's health and the "important and legitimate interest in protecting the potentiality of human life." Thus, a State may "proscribe abortion [after viability], except when it is necessary to preserve the life or health of the mother." *Id. Roe* also recognized that States have a "legitimate interest in seeing to it that abortion, like any other procedure, is performed under circumstances that ensure maximum safety for the patient." *Id*. at 150.

In *Planned Parenthood of Southeastern Pennsylvania v. Casey*, 505 U.S. 833 (1992), the Court replaced *Roe*'s trimester framework with a bifurcated pre-viability/post-viability framework and applied a new "undue burden" standard (related to abortion *patients*, but not to abortion *physicians*) to gauge the constitutionality of abortion restrictions. The Court specifically acknowledged that "the State has legitimate interests from the outset of the pregnancy in protecting the health of the woman and the life of the fetus that may become a child." *Id.* at 846. Further, the Court reaffirmed *Roe*'s holding that "subsequent to viability, the State in promoting its interest in the potentiality of human life may, if it chooses, regulate, and even proscribe, abortion except where it is necessary, in appropriate medical judgment, for the preservation of the life or health of the mother." *Id.* at

878-79 (quoting *Roe*, 410 U.S. at 164-65). The controlling plurality in *Casey* held that an abortion regulation would be unconstitutional if "*in a large fraction of cases* in which [the challenged requirement] is relevant, it will operate as a substantial obstacle to a woman's choice to undergo an abortion." *Id. at* 895. (emphasis added).

Finally, in *Gonzales v. Carhart*, 550 U.S. 124 (2007), the Supreme Court rejected challenges by Planned Parenthood and abortionist Leroy Carhart to the federal Partial-Birth Abortion Ban Act. The Court said: "The Act's stated purposes are protecting innocent human life from a brutal and inhumane procedure and protecting the medical community's ethics and reputation. The government undoubtedly 'has an interest in protecting the integrity and ethics of the medical profession.'" *Id.* at 128 (citing *Washington v. Glucksberg*, 521 U.S. 702, 731 (1997). *Gonzalez* further acknowledged that States have "wide discretion in passing legislation in areas where there is medical and scientific uncertainty." *Id*. at 163.

Therefore, in order to succeed on its facial challenge to the requirements of H.B. 2, plaintiffs here must show, at the very least, that in a "large fraction" of cases, the law operates as a "substantial obstacle." This, they have not done. Neither have plaintiffs demonstrated that H.B. 2 is unconstitutional as applied,

particularly given that that focus of the constitutionality is on the treatment of women, *not* on the financial convenience of abortion providers.

A. There are risks associated with all abortion procedures.

Any medical procedure inherently carries risks to patients. Abortion is a medical procedure that poses significant known and potential risks to women. Serious long-term health risks have been well-documented in a peer-reviewed abstract of abortion-related health studies over the first thirty years of legalized abortion. *See* J.M. Thorp, Jr., M.D.,[4] et al., *Long-Term Physical & Psychological Health Consequences of Induced Abortion: Review of the Evidence*, 58 OB/GYN SURVEY 67 (2003) ("the OGS Review"). The OGS Review evaluated over sixty international studies that included more than one million women. Based on extensive data, the OGS Review concluded that induced abortion is associated with significantly increased risks of long-term physical and psychological health conditions, including serious mental health disorders/suicide, placenta previa, preterm birth, and breast cancer.[5]

The Texas "A Woman's Right to Know" booklet ("WRTK Booklet"), which Texas requires be provided to all women seeking abortions, identifies the

[4] Dr. Thorp was an expert for the State in the prior litigation involving H.B. 2. *See* State Defendants' Trial Brief, at Exh. 4, *Planned Parenthood of Greater Tex. Surgical Health Servs. v. Abbott*, No. 1:13-cv-862 (Oct. 15, 2013).

[5] A summary of the OGS Review findings as presented to the U.S. Supreme Court in an amicus brief filed by Bioethics Defense Fund on behalf of Dr. Thorp can be found at http://www.bdfund.org/uploads/file_637.pdf.

potentially dire short-term risks associated with both surgical and medication abortions, including death, incomplete abortion (fetal body parts left in the woman), hemorrhage (profuse or uncontrolled bleeding), allergic reaction, respiratory problems, infection, uterine perforation or rupture, cervical laceration, and injury to the bowel or bladder. The WRTK Booklet informs that post-abortion emergency treatment may include surgery including hysterectomy, medical treatment, and blood transfusion. The WRTK Booklet directs women to seek emergency care if, following an abortion, they experience: heavy bleeding, severe or uncontrolled pain, fever, difficulty breathing or shortness of breath, chest pain, or disorientation. *See* Texas Department of Health, A WOMAN'S RIGHT TO KNOW, http://www.dshs.state.tx.us/wrtk/.

B. Medication abortions pose even greater risks to women's health and safety than do surgical abortions.

While the term "abortion" is most often associated with surgical abortions, "medication" abortions are prevalent in Texas and other States. Medical abortions are accomplished by administering medications such as mifepristone and misoprostol to terminate a pregnancy. H.B. 2 requires that the FDA-approved protocol for the administration of such abortifacient drugs be satisfied. Texas Health & Safety Code § 171.063(a). While this specific provision is not at issue in this appeal and was upheld in *Planned Parenthood of Greater Tex. Surgical Health*

Servs. v. Abbott, 748 F.3d 583, 604-605 (5th Cir. 2014) ("*Abbott II*"), the district court nonetheless and improperly considered medication abortions in its decision.

With no factual support, and although there is substantial scientific support to the contrary, the district court concluded that "[t]he imposition of [ASC] requirements [on abortion facilities] is even weaker in the context of medication abortions, where no surgery is involved." *Whole Woman's Health v. Lakey*, 2014 WL 4346480 at *9 (W.D. Tex. Aug. 29, 2014). The district court, without acknowledging the substantial scientific support that identifies even greater risks to women's health and safety from medication abortions, incorrectly concluded that "no surgery or physical intrusion into a woman's body occurs during" medication abortions, whereas in fact approximately 1 out of 20 women require post-abortion surgery to complete a failed medication abortion and that number is increased for gestational ages over 49 days. The district court dismissed (or failed to consider) the seriousness of the medication abortion procedure as though post-medication abortion complications and health and safety concerns are either non-existent or may be minimized. *Id*. at *6. In fact, medication abortions involve substantial risks to the health and safety of women and Texas has a legitimate interest in regulating such abortions and the facilities in which they occur, just as it has in regulating surgical abortions.

The health risks associated with medication abortions are acknowledged by both the U.S. Food and Drug Administration (FDA) and the manufacturers of both Mifeprex and misoprostol.[6] The American College of Obstetricians & Gynecologists (ACOG) has also acknowledged these risks in ACOG Practice bulletins published in 2005 (and reaffirmed in 2011). *See, e.g.*, *ACOG Practice Bulletin 67: Medical Management of Abortion* 4-6 (Oct. 2005, reaffirmed 2011).

The largest and most accurate study of medication abortions was published in 2009 and consists of a review of medical records from 22,368 women who were administered medication abortions using predominantly off-label mifepristone and misoprostol dosing, compared with 20,251 women underwent surgical abortions. According to this study, the "overall incidence of adverse events was fourfold higher in" medication abortions than in surgical abortions. *See* M. Niinimäki et al., *Immediate Complications after Medical compared with Surgical Termination of Pregnancy*, OBSTET. GYNECOL. 114:795 (Oct. 2009). These "adverse events," or risks, included hemorrhaging, incomplete abortions, surgical re-evacuation, and injuries requiring post-abortion operative treatment. According to the study, the rate of occurrence for all of these adverse events was higher with medical abortions than it was with surgical abortions. *Id.*

[6] Misopristol (Cytotec) FPL, available at *www.accessdata.fda.gov.*

In addition to these risks, the FDA-approved Mifeprex final printed labeling (FPL) warns that "[n]early all of the women who receive Mifeprex and misoprostol will report adverse reactions, and many can be expected to report more than one such reaction." Mifeprix FPL, available at http://www.accessdata.fda.gov. The Mifeprix FPL itself states that "about 90% of patients report adverse reactions following administration of misoprostol on day three of the treatment procedure." *Id.* at 11. These risks include, but are not limited to, abdominal pain, cramping, vomiting, headache, fatigue, uterine hemorrhage, viral infections, anemia, and pelvic inflammatory disease. *Id*. at 12 (Table 3).

As of August 2008, six women had died from bacterial infection following medication abortions. *See* U.S. Government Accountability Office, *Food and Drug Administration: Approval and Oversight of the Drug Mifeprex* 38 (Aug. 2008). Subsequently, the number of complications—including deaths—has increased. In July 2011, the FDA reported 2,207 cases of adverse events after using mifepristone for the termination of pregnancy. FDA, *Mifepristone U.S. Postmarketing Adverse Events Summary Through 04/30/2011* (July 2011). Among the 2,207 adverse events were 14 deaths, 612 hospitalizations, 339 blood transfusions, and 256 infections (including 48 "severe infections"). *Id*. It is also important to note that many potential complications that result from use of the Mifeprex regimen are unknown due to widespread inadequacies in reporting. *See* D.A, Kessler, *A New*

Approach to Reporting Medication and Devise Adverse Effects and Product Problems, JAMA 269: 2765 (1993).

Despite these reporting inadequacies, there are several methodologically sound studies based on complete, actual medical records of women who have had medication abortions. These large registry-based studies also demonstrate that there are more complications from medication abortions than from surgical abortions. A major review of nearly 7,000 abortions performed in Australia using off label regimens in 2009 and 2010 found that 3.3 percent of patients who used mifepristone in the first trimester required emergency hospital treatment, in contrast to 2.2 percent of patients who underwent surgical abortions. See E. Mulligan & H. Messenger, *Mifepristone in South Australia: The First 1343 Tablets*, AUSTRALIAN FAMILY PHYSICIAN 40(5):342-45 (May 2011). Women receiving medication abortions were admitted to hospitals at a rate of 5.7 percent following the abortion, as compared with 0.4 percent for patients undergoing surgical abortion. *Id.* at 343. Thus, evidence demonstrates that women are more likely to be admitted and require emergency intervention after a first trimester medication abortion than after a surgical abortion.

Additionally, research demonstrates that medication abortions present greater risks of death from Clostridium sordellii sepsis than do surgical abortions. As discussed in articles by Mark Fischer of the Centers for Disease Control and

Prevention (CDC) and Michael Greene, the risk of death from C. sordellii infection during a mifepristone abortion is at least ten times the risk of death from all types of infection after surgical abortion. *See* M. Fischer et al., *Fatal Toxic Shock Syndrome Associated with Clostridium sordellii after Medical Abortion*, N.E.J.M. 353:2352, 2358 (2005); M.F. Greene, *Fatal Infections Associated with Mifepristone Induced Abortion*, N.E.J.M. 353:2317-2318 (Dec 1, 2005). Significantly, Fischer reported no deaths from C. sordellii following surgical abortions in his review of C. sordellii infections from 1997 to 2001. Thus, it is evident that medication abortions present much greater risks of life-threatening infections than do surgical abortions.

In addition to the evidence demonstrating that medication abortions have greater risks of fatal infections than do surgical abortions, other serious complications from misoprostol, including acute hemolytic anemia after misoprostol for medication abortions have been documented and reported. *See* A. Filippini et al., *Acute hemolytic anemia with acanthocytosis associated with high-dose misoprostol for medical abortion*, ANN. EMERG. MED., 50(3):289-91, and fatal septic[7] shock. *See* F. Cittadini et al., *A Case of Toxic Shock due to Clandestine Abortion by Misoprostol self-administration*, J. FORENSIC SCI. 10.1111/1556-4029.12536 (July 2014).

[7] Mifeprex FPL, available at *www.accessdata.fda.gov*.

Of all these risks, the greatest risk is that of hemorrhage. Hemorrhage needs to be managed quickly to avoid life-threatening blood loss. A post-abortion woman will understandably seek treatment and management for hemorrhage from the abortion facility which provided her the abortion. Thus, abortion facilities simply must be properly equipped and staffed to manage life-threatening hemorrhages. In support of this fact, the ACOG PB 67, reaffirmed in 2011, states:

> Still, just as for women undergoing surgical abortion, surgical curettage must be available on a 24 hour basis for cases of hemorrhage. Clinicians who wish to provide medical abortion services either should be trained in surgical abortion or should work in conjunction with a clinician who is trained in surgical abortions.

This ACOG statement recognizes the sudden and severe nature of hemorrhage which can take place and the need for a woman to be able to access an abortion facility prepared to deal with such emergency situations. That is the reason Texas may properly require abortion facilities to meet ASC requirements. These are, after all, the standard of care for facilities which must deal with these surgical emergencies.

C. Texas has recognized the risks associated with all abortions and has taken steps to protect women's health and safety by regulating abortions.

Texas, as many other States[8], has clearly recognized the risks associated with both surgical and medication abortions and has taken steps to regulate these abortions to minimize these known and potential risks and to protect women's health and safety. Texas now is (and should continue to be) permitted to do so.

1. Existing regulation of abortion facilities in Texas.

Due to the significant health and safety risks to women, well before H.B. 2, Texas regulated abortions and abortion facilities consistent with *Roe* and its progeny. It has done so in a regime that was, until H.B. 2, distinct from its regulation of ASCs. *See* TEX. ADMIN. CODE § 139.1 *et seq.* Texas defines abortion facilities as facilities that perform abortions, excluding licensed hospitals, ASCs, and physician offices that perform 50 or fewer abortions per year. Texas law also requires abortion facilities to be licensed, *see id.* at § 139.1-139.2, and to maintain a quality assurance program implemented by a quality assurance committee, *see id.* at § 139.8. Abortion facilities must be fully inspected by an on-site, unannounced inspection at least once per year, *see id.* at § 139.31. Notably, *even before* the

[8] Numerous states across the country regulate abortions, and some states require some or all abortion providers to meet ASC standards. See, e.g., MO.STAT. ANN. § 197.200, 28 PA. CODE § 294.43(a), VA. CODE ANN. § 32.1-127. According to Guttmacher Institute, 23 states require facilities where abortions are performed to meet standards "intended for" ASCs. Guttmacher Institute, State Policies in Brief: Targeted Regulation of Abortion Providers, As of November 4, 2014, available at: www.guttmacher.org/statecenter/spibs/spib_TRAP.pdf.

Texas Legislature enacted H.B. 2, Texas required abortion facilities either to have a physician with admitting privileges at a local hospital or to have a working arrangement with an outside physician who had those privileges so as to ensure that abortion facilities could provide appropriate follow-up patient care when necessary. *See id.* at § 139.56.

2. Texas abortion facilities' poor record of patient care demonstrates the need for additional regulation.

Documented experiences at abortion facilities in Texas illustrate the legitimacy of Texas's concerns regarding care for women. Inspections of Texas abortion facilities over the past few years have documented numerous deficiencies, including, lack of staff training; lack of sterilization; lack of medical personnel; lack of emergency medication and procedures; expired credentials, equipment, and medication; not following the emergency procedures that did exists; lack of recordkeeping on an otherwise-documented emergency; lack of follow-up with patients; a hole in the middle of an abortion room floor; another hole that "had the likelihood to allow rodents to enter the facility" and "puncture the sterilization" supplies; "numerous rusty spots" on a suction machine which had "the likelihood to cause infection"; a total lack of proper medication dispensation; a disconnected defibrillator cable and lack of staff knowledge about how to use it; unidentified liquids in operating rooms; the use of "ineffective"-strength sterilization solution; and abortions outside the gestational range. *See* Texas DSHS Statements of

Deficiencies and Plans of Correction with various dates from 2011-2013, *available at* http://www.lifenews.com/2013/10/28/texas-abortion-chain-running-filthy-clinics-rusty-blood-stains-on-suction-machines/. When questioned, one employee said it was just too expensive to maintain a sanitary environment: "The functional check is more expensive and the facilities do not want to pay for the functional check." *Id.* In short, the facilities failed to provide a safe environment. At another facility, there was no hand washing and no one in charge of medical decisions, and employees were observed handling tissue and body fluids, and drawing up medications and sterilizing instruments at the same time, without washing hands or wearing gloves. *See* Texas DSHS Statement of Deficiencies and Plan of Correction (5/23/2013), *available at* http://prolifeaction.org/docs/2013/2013-05-23AlamoWomens.pdf.

At Whole Woman's Health Beaumont, a facility run by a plaintiff in this case, state health inspectors reported in October 2013 that, "[b]ased on observation and interview, the facility failed to provide a safe environment for patients and staff." Inspectors documented numerous deficiencies at the abortion facility. *See* Texas DSHS Statement of Deficiencies and Plan of Correction, October 3, 2013, available at https://www.lifesitenews.com/news/inspections-find-notorious-texas-abortion-chain-running-filthy-clinics-desp.

3. Texas House Bill 2 was designed to further protect the health and safety of women seeking abortions.

In this context, the Texas Legislature passed H.B. 2 with the overarching purpose of strengthening existing health and safety regulations for women. H.B. 2, *inter alia*, adds TEX. HEALTH & SAFETY CODE § 171.0031 which requires that an abortionist must, on the date the abortion is performed or induced, "have active admitting privileges at a hospital that is located not further than 30 miles from the location [of the abortion]; and provides obstetrical or gynecological health care services," and further, provide the pregnant woman with contact information for the physician or another medical employee of the facility with access to the woman's relevant medical records, available 24 hours a day, and the name and telephone number of the hospital nearest to the woman's home. The clear purpose of this requirement is for all doctors performing abortions to be able to admit those women to a hospital in the event of emergency post-abortion complications. *See id.*

Additionally, H.B. 2 requires that abortion facilities comply with the same minimum health and safety standards as do ASCs. TEX. HEALTH & SAFETY CODE § 245.010. *See also* 25 TEX. ADMIN. CODE § 135 et seq. (setting forth regulatory standards for ASCs).

These provisions of the H.B. 2 are clearly designed to protect the health and safety of women by ensuring that every abortion patient in Texas has access to a doctor familiar with her particular case at every step of the process and recovery

and that all abortions are performed in facilities that meet the same minimum health and safety standards as do ASCs.

II. As the Fifth Circuit has already concluded, the admitting privileges requirement of House Bill 2 is constitutional.

This Circuit has already found constitutional H.B. 2's admitting privileges requirement again at issue in this case. *See Planned Parenthood of Greater Tex. Surgical Health Servs. v. Abbott*, 748 F.3d 583, 604-605 (5th Cir. 2014). There is no evidence in the record to support the proposition that this Court should reach any different conclusion here, either on a facial or an as-applied challenge basis. Additionally, as the motions panel noted, despite the fact that plaintiffs in this case sought only as-applied relief with regard to the admitting privileges requirement, the district court issued a statewide injunction. *Whole Woman's Health v. Lakey*, 2014 WL 4930907 at *2 (5th Cir. Oct. 2, 2014)[9]. That ruling was "directly contrary to this circuit's precedent." *Id.* at 4. See also *Jackson Women's Health Org. v. Currier*, 760 F.3d 448, 458 (5th Cir. 2014) (limiting injunction issued by district court to the scope of relief sought by plaintiffs).

A. The admitting privileges requirement is rationally related to a legitimate state interest.

In *Abbott*, the admitting privileges requirement of H.B. 2 was found to satisfy the rational basis standard of review which is satisfied if the law at issue is

[9] On October 14, 2014, the Supreme Court, without explanation, vacated the Fifth Circuit's stay order. *Whole Woman's Health v. Lakey*, 2014 WL 5148719 (U.S. Oct 14, 2014) (NO. 14A365).

rationally related to a legitimate State interest. 748 F.3d at 594-596. See *City of Cleburne v. Cleburne Living Ctr.*, 473 U.S. 432, 440 (1985). Moreover, even the district court below concluded in this case that the admitting privileges requirement "surmount[s] the low bar of rational-basis review." *Whole Woman's Health*, 2014 WL 4346480 at *4.

Admitting privileges promote both the physical and the emotional well-being of patients. Admitting privileges are important and even necessary in emergency circumstances in order to provide an acceptable level of care to a patient in need. If an abortion doctor is not involved in the admission of a patient experiencing post-abortion complications, a failure to timely convey information about the woman's medical history and the details of her abortion procedure can result in significant time delays that could compromise her health, both physical and emotional, or lead to her death. Likewise, many hospitals have inadequate on-call coverage by OB/GYNs. *See, e.g.*, Center for Studying Health System Change, *Hospital Emergency On-Call Coverage: Is There A Doctor in the House?* (November 2007), http://www.hschange.com/CONTENT/956/.

Given the district court's concession that the requirement is rationally related to a legitimate state interest and that this conclusion was not challenged on appeal, *amici* need not elaborate further on this aspect.

B. The admitting privileges requirement does not impose an "undue burden."

As the facial challenge of the admitting privileges requirement was rejected in *Abbott II*, 748 F.3d at 599-600, and plaintiffs in this case brought an as-applied challenge to this same admitting privileges requirement, the district court's authority, at most, was limited to analyzing the alleged undue burden as to these specific plaintiffs and to their specific abortion facilities in McAllen and El Paso, Texas.

To establish an undue burden plaintiffs must show that the admitting privileges requirement had the "purpose or effect [] to place a substantial obstacle in the path of a woman seeking an abortion." *Gonzales*, 550 U.S. at 146 (quoting *Casey*, 505 U.S. at 878). According to *Casey*, plaintiffs would have to show that the statute operates as a "substantial obstacle" in a "large fraction of the cases in which it is relevant." *Casey*, 505 U.S. at 895.

First, with regard to the "purpose," there is no evidence in the record of any improper motive on the part of the Texas Legislature in enacting H.B. 2. *See Mazurek v. Armstrong*, 520 U.S. 968, 972 (1997) (requiring *evidence* of improper legislative purpose). There is also no evidence that patients in McAllen or El Paso, or anywhere else in Texas, have been unable to obtain abortions or have faced a "substantial obstacle" in seeking an abortion as a result of the admitting privileges requirement. Moreover, the district court below failed to cite any evidence as to

why doctors associated with plaintiffs were not able to obtain admitting privileges as required by H.B. 2 or even why this requirement was unconstitutional as applied to them specifically.

Although the admitting privileges requirement went into effect in October 2013, abortion clinics have remained open in many areas in Texas. *Whole Woman's Health*, 2014 WL 4930907 at *13. Nonetheless, the district court noted that "[b]etween November 1, 2012 and May 1, 2014, the decrease in geographic distribution of abortion facilities has required a woman seeking an abortion to travel increased distance." *Whole Woman's Health*, 2014 WL 4346480 at *6. However, the record indicates and as argued by the government, some Texas abortion facilities closed for reasons entirely unrelated to H.B. 2.[10] ROA.3923-24.

Moreover, mere increases in travel distances do not constitute an "undue burden." *Abbott*, 734 F.3d at 415. Even accepting the opinion of plaintiffs' expert that approximately 16.7% of women seeking an abortion live more than 150 miles from the nearest abortion clinic, 17%, as noted by the motions panel, hardly constitutes a "large fraction." *Whole Woman's Health*, 2014 WL 4930907 at *9.

[10] For example, the Planned Parenthood abortion facility in Lubbock (included by plaintiffs' expert in his calculations) were bought out in an "asset transfer" by Generation Healthcare, a non-profit group headed by an adoption attorney. Abortions were discontinued for reasons unrelated to H.B 2 or *Abbott II*. See *Lubbock Abortion Clinic Taken Over, Abortions to Stop*, available at http://www.everythinglubbock.com/story/lubbock-abortion-clinic-bought-out-abortions-to-stop/d/story/K226KmsOcE-R-iMIYW3g1w.

In *Casey*, the Supreme Court upheld a law that, according to the lower court, required women in 62 of Pennsylvania's 67 counties to travel at least one hour and sometimes more than three hours to the nearest abortion facility, finding that such did not constitute an undue burden. *Abbott II*, 748 F.3d. at 598 (citing *Planned Parenthood of Se. Pa. v. Casey*, 744 F. Supp. 1323, 1352 (E.D.Pa.1990), *aff'd in part, rev'd in part*, 947 F.2d 682 (3d Cir.1991), *aff'd in part, rev'd in part*, 505 U.S. 833 (1992)).

There is simply no evidence in the record to demonstrate that the admitting privileges requirement, as applied in this case, constitutes an undue burden. To succeed on such a challenge, a plaintiff must present actual evidence, not hypothetical scenarios or conjecture, that prove a substantial burden. This, plaintiffs have failed to do.

Given the undisputed conclusion that the admitting privileges requirement satisfies rational basis review, which necessarily means it is reasonably related to a legitimate state interest, the question remains as to why there should be an exception to the level and quality of medical care for women who live in rural areas as opposed to women who live in urban areas, as apparently urged by plaintiffs. The same post-abortion medical, health and safety concerns are experienced by women who live in rural areas as are experienced by women who live in urban locales. It is unacceptable for women in rural locations to be forced to

accept sub-standard care because the laws designed to protect them were suspended to accommodate abortion providers. Women may need to drive longer distances to obtain quality care until abortion providers who comply with the law are "closer" to them, but there are a sufficient number of abortion facilities in Texas to accommodate these women and these facilities can and should be held to the standard of care established by Texas.

With regard to travel distances, *amici* urge this Court to adopt a bright line standard such as that adopted by the Eighth Circuit so as not to be required to make an ad hoc determination in each case as to whether a particular distance is "too far." In the Eighth Circuit, no travel distance within the state is "too far." *Fargo Women's Health Org. v. Schafer*, 18 F.3d 526, 533 (8th Cir. 1994) ("We do not believe a telephone call and a single trip, whatever the distance to the medical facility, create an undue burden."). Such bright line rule would eliminate the need for courts in the Fifth Circuit to involve themselves in issues of distances and how far is too far, particularly when, by all accounts, there are numerous abortion facilities in existence throughout the State.

A bright line standard would also prevent federal courts from being tasked with permanently monitoring the status of specific abortion providers. If, as plaintiffs urge, an "undue burden" is to be adjudged by using a clinic-by-clinic, mile-by-mile, provider-by-provider assessment of the geographical availability of

abortions and the patient capacity of existing abortion facilities, then the parties, both plaintiffs and Texas, would be entitled to seek modifications of a "permanent" injunction whenever, on the one hand, a current abortion provider retires, dies, moves out of state, or otherwise becomes unavailable, or, on the other hand, a potential new abortion provider with admitting privileges comes on the scene.[11]

Indeed, Texas has more than enough existing abortion providers to provide abortions throughout the State, even in those areas the district court seemed most concerned with, *i.e.,* El Paso and McAllen, Texas[12]. There are several hospitals in both of those areas and scores of doctors with admitting privileges to those hospitals. The obstacle abortion clinics face in those communities is not a shortage of eligible doctors, but a shortage of eligible doctors who appear to be willing to perform abortions. Thus, if there is a burden on women who may seek an abortion in those areas, the burden is caused not by Texas unduly restricting the number of eligible doctors, but by the unwillingness of most eligible doctors to perform abortions.

[11] This same analysis is true with regard to ACS requirements discussed in Section III.

[12] In the absence of a bright line standard that no distance within the state is too far, on an as-applied challenge, the Court should look at the actual facts of a particular situation. Here, it is beyond dispute that there is an abortion provider in Santa Teresa, New Mexico which is less than one mile from the Texas border and part of the same metropolitan area as El Paso. ROA.3924.

III. The requirement of H. B. 2 that abortion facilities meet the same minimum health and safety standards as ASCs is also constitutional.

H. B. 2 included a requirement that "the minimum standards for an abortion facility must be equivalent to minimum standards adopted under [TEXAS HEALTH & SAFETY CODE] Section 243.010 for ambulatory surgical centers." TEX. HEALTH & SAFETY CODE § 245.010(a); 25 TEX. ADMIN. CODE § 139.40. This common sense requirement that Texas abortion facilities meet the same minimum health and safety standards as Texas ASCs is constitutional as well.

A. The ASC requirement is rationally related to a legitimate state interest.

The district court below concluded that the ASC requirement "surmount[s] the low bar of rational-basis review." *Whole Woman's Health*, 2014 WL 4346480 at *4. Given this concession that the requirement is rationally related to a legitimate State interest and that this conclusion was not challenged on appeal, *amici* will not elaborate further on this aspect of the analysis.

B. The ASC requirement does not impose an "undue burden."

Given the unchallenged conclusion that the ASC requirement is rationally related to a legitimate State interest, the question then becomes whether such a requirement constitutes an "undue burden." Again, a law cannot be facially invalid unless it constitutes an "undue burden" in "a large fraction of relevant cases." *Gonzales*, 550 U.S. at 167-78; *Planned Parenthood of Greater Tex. Surgical*

Health Servs. v. Abbott, 734 F.3d 406, 414 (5th Cir. 2013); *Abbott II*, 748 F.3d at 588-89.

The ASC requirements appear in Chapter 135 of Title 25 of the TEXAS ADMINISTRATIVE CODE. There are three categories of regulatory standards that apply: operating requirements, fire prevention and safety requirements, and physical plant and construction requirements. These regulations are clearly designed to protect health and safety of patients and others.

Despite the protestations of plaintiffs that they cannot possibly remain in business and comply with these regulations, many of these regulations can easily be complied with and, if abortion providers are at all interested in promoting the best interests of women. Such regulations should already have been voluntarily implemented. For example, certain of the regulations establish patient rights, including the right to be "treated with respect, consideration, and dignity," to be "provided with appropriate privacy," to be provided with "appropriate information concerning their diagnosis, treatment, and prognosis," and a host of other common sense provisions. 25 TEX. ADMIN. CODE § 135.5. Another regulation requires that "[a]dministrative policies, procedures and controls shall be established and implemented to assure the orderly and efficient management of the ambulatory surgical center…" 25 TEX. ADMIN. CODE § 135.6. Healthcare practitioners are required to have "the necessary and appropriate training and skills to deliver the

services provided." 25 TEX. ADMIN. CODE § 135.7. While the financial concerns of the district court seemed to be focused on the construction requirements contained in 25 TEX. ADMIN. CODE § 139.40, that is but one small portion of the regulations, and conflicts with the district court's broad injunction finding that the entire "ambulatory-surgical-center requirement is unconstitutional." *Whole Woman's Health*, 2014 WL 4246480 at *12.

While there is no evidence in the record to support its conclusion, the district court, applying neither the "no set of circumstances" test of *Barnes v. Mississippi*, 992 F.2d 1335, 1342 (5th Cir. 1993) nor *Casey*'s "large fraction" test, relied on the amorphous assertion that "a significant number of the reproductive age female population of Texas will need to travel considerably further" to obtain an abortion. *Whole Woman's Health*, 2014 WL 4346480 at *6. This should not stand.

CONCLUSION

For the foregoing reasons, *amici* urge the Court to reverse the judgment of the district court.

Respectfully submitted this the 10th day of November, 2014.

By: s/ Michael J. Norton

Michael J. Norton
Counsel of Record for Amici Curiae
Natalie L. Decker
ALLIANCE DEFENDING FREEDOM
7951 E. Maplewood Ave., Suite 100
Greenwood Village, CO 80111
Telephone: (720) 689-2410
Facsimile: (303) 694-0703
mjnorton@alliancedefendingfreedom.org
ndecker@alliancedefendingfreedom.org

Catherine Short
LEGAL DEFENSE FOUNDATION
P.O. Box 2105
Napa, CA 94558
Telephone: (707) 224-6675
Facsimile: (707) 224-6676
LLDFOjai@cs.com

Stephen Casey
Gregory R. Terra
TEXAS CENTER FOR DEFENSE OF LIFE
501 S. Austin Ave., Suite 1130
Georgetown, Texas 78626
Telephone: (512) 763- 9068
Stephen@tcdl.org
greg@tcdl.org

Steven H. Aden
Catherine Glenn Foster
ALLIANCE DEFENDING FREEDOM
801 G Street NW, Suite 509
Washington, DC 20001
Telephone: (202) 393-8690
saden@alliancedefendingfreedom.org
cfoster@alliancedefendingfreedom.org

CERTIFICATE OF SERVICE

I hereby certify that on November 10th, 2014, I caused the foregoing Amicus Curiae Brief to be electronically with the Clerk of the Court for the United States Court of Appeals for the Fifth Circuit by using the CM/ECF system. Participants in the case are registered CM/ECF users and service will be accomplished by the CM/ECF system.

s/ Michael J. Norton
Counsel of Record for Amici Curiae

CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATION, TYPEFACE REQUIREMENTS, AND TYPE STYLE REQUIREMENTS

1. This brief complies with the type-volume limitation of FED. R. APP. P. 32(A)(7)(B) because this brief contains 6,889 words, excluding the parts of the brief exempted by FED. R. APP. P. 32(a)(7)(B)(iii).

2. This brief complies with the typeface requirements of FED. R. APP. P. 32(a)(5) and the type style requirements of FED. R. APP. P. 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Word 2007 Times New Roman 14 point font.

s/ Michael J. Norton
Counsel of Record for *Amici Curiae*

Dated: November 10, 2014